UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,345	06/09/2006	Takashi Uemori	UEMORI3	4978

1444 7590 08/05/2009

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
CALAMITA, HEATHER	
ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
08/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,345	UEMORI ET AL.	
	Examiner	Art Unit	
	HEATHER G. CALAMITA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 8 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. Claims 1-5, 8 and 10 are pending and under examination. Per the telephonic interview with Applicants on July 16, 2009, finality of the Office Action issued on April 2, 2009, has been withdrawn. Any objections and rejections not reiterated below are hereby withdrawn. This action is NON-FINAL.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 8 and 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cleuziat et al. (USPN 5,824,517) in view of Kacian et al. (USPN 5,916777).

With regard to claim 1, Cleuziat et al. teach a method for amplifying a nucleic acid, the method comprising the steps of:

(A) preparing a reaction mixture

(b) a nucleic acid as a template a deoxyribonucleotide triphosphate, a DNA polymerase having a strand displacement activity, at least two chimeric oligonucleotide primers and an RNase H, wherein one of the chimeric oligonucleotide primers serves a s a ladder-forming oligonucleotide primer (see col. 6 line 41 to col. 7 line 31, where, two chimeric primer, RNase H, a DNA polymerase having strand displacement activity is used. Additionally, one of the chimeric primers serves as a ladder-forming primer as this primer meets the requirements outlined in the instant specification in paragraphs 0054 and 0055. See also col. 11 lines 10 to col. 12 line 66).

wherein each chimeric oligonucleotide primer contains a ribonucleotide as well as at least one selected from the group consisting of a deoxyribonucleotide and a nucleotide analog (see the abstract and col. 6 lines 7-9)

wherein the chimeric oligonucleotide primers comprise at least a first chimeric oligonucleotide primer which is complementary to a nucleotide sequence of the nucleic acid as a template and a second chimeric oligonucleotide primer which is homologous to a nucleotide sequence of the nucleic acid as a template, (see col. 6 line 41 to col. 7 line 31 and also col. 11 lines 10 to col. 12 line 66)

wherein the ladder-forming oligonucleotide primer has a sequence complementary to a region of the nucleic acid as a template that is complementary to the first chimeric oligonucleotide primer and/or a nucleotide sequence 3' to said region and has on its 5' side, a sequence complementary to a nucleotide sequence on the 5' side of the second chimeric oligonucleotide primer which is homologous to the nucleic acid template; a nucleotide sequence of the nucleic acid as a template corresponding to a region 5' to the 5' terminus of the portion homologous to the second chimeric oligonculeotide primer; or both (see col. 6 lines 41- col. 7 line 31 and also col. 11 lines 10 to col. 12 line 66)

(B) incubating the reaction mixture for a sufficient time to generate a ladder-like amplification product under constant-temperature conditions under which specific annealing of the primer to the nucleic acids as a template, a reaction of synthesizing an extended strand and a strand displacement reaction by the DNA polymerase, as well as a reaction of cleaving an extended strand by RNase H take place (see col. 6 lines 41- col. 7 line 31 and also col. 11 lines 10 to col. 12 line 66, where ladder-like products are generated necessarily because of the presence of the ladder-forming primer, as defined in the instant specification)

With regard to claim 2, Cleuziat et al. teach the nucleic acid template is RNA and the nucleic acid is treated beforehand with a dntp, a DNA polymerase having a reverse transcription activity and at least

one ladder-forming oligonucleotide primer to convert the nucleic acid into a reverse transcription product (see col. 6, lines 1-40, where the template can be RNA or DNA).

With regard to claim 3, Cleuziat et al.teach wherein the reaction mixture in step (A) further contains a DNA polymerase having reverse transcription activity (see col. 6 lines 31-37)

With regard to claim 4, Cleuziat et al. teach the nucleic acid template is an mRNA (see col. 8 lines 47-56, where total nucleic acid isolation is discussed and total RNA necessarily includes mRNA)

With regard to claim 5, Cleuziat et al. teach a single DNA polymerase having reverse transcription activity and strand displacement activity (see col. 6 lines 31-37)

With regard to claim 8, Cleuziat et al. teach a method for amplifying a nucleic acid, the method comprising the steps of:

(a) amplifying a target nucleic acid according to the method for amplifying a nucleic acid defined by claim 1 and (see citations for rejected claim 1, as they all apply here)

(b) detecting the amplified target nucleic acid (see col. 8 line 45, where Cleuziat disclose detecting target nucleic acids).

Cleuziat et al. do not teach all of the limitations of the instant claims. Specifically, Cleuziat et al. do not teach the ribonucleotide is positioned at the 3' terminus or on the 3'terminal side of the primer [claims 1 and 10].

Kacian et al. teach positioning a ribonucleotide at the 3' terminus of a chimeric primer (see the abstract and col. 9 lines)

It would have been prima facie obvious to place the ribonucleotide at the 3' terminus of a chimeric primer as disclosed by Kacian et al. and use the primer in a DNA amplification method as disclosed by Cleuziat et al. because Kacian et al. teach DNA primers with ribonucleotides at the 3' terminus is used to prevent contamination during PCR and that it also provides a convenient cleavage site for separation of the primer form the oligonculeotide product. An ordinary practitioner would have been

motivated to place the ribonucleotide at the 3' terminus of a chimeric primer as disclosed by Kacian et al. and use the primer in a DNA amplification method as disclosed by Cleuziat et al. in order to amplify DNA while reducing the risk of contamination during the amplification process and facilitate separation of the primer from the resulting product.

Summary

3. No claims were allowed.

Correspondence

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Heather G. Calamita/
Examiner, Art Unit 1637